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10/575,333

04/12/2006

Nicolas Bihoreau

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EXAMINER

GUSSOW, ANNE

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

12/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/575,333 | Applicant(s) BIHOREAU ET AL. | |
| | Examiner ANNE M. GUSSOW | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 and 33-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/30/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group V, claims 28-32 in the reply filed on September 2, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-27 and 33-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 2, 2008.
3. Claims 28-32 are under examination.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on October 30, 2008 has been fully considered by the examiner and an initialed copy of the IDS is included with the mailing of this Office Action.

Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it is filed in a foreign language and is not accompanied by an English translation. Applicant is directed to 37 CFR 1.69 regarding foreign language oaths (see below).

§ 1.69 Foreign language oaths and declarations.

(a) Whenever an individual making an oath or declaration cannot understand English, the oath or declaration must be in a language that such individual can understand and shall state that such individual understands the content of any documents to which the oath or declaration relates.

(b) Unless the text of any oath or declaration in a language other than English is in a form provided by the Patent and Trademark Office or in accordance with PCT Rule 4.17(iv), it must be accompanied by an English translation together with a statement that the translation is accurate, except that in the case of an oath or declaration filed under § 1.63, the translation may be filed in the Office no later than two months from the date applicant is notified to file the translation.

The time period for filing the English translation is TWO MONTHS from the mailing date of this Office Action. This is a separate time period from the time to reply to the Office Action.

Specification

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. The hyperlink is located on page 7.

Claim Objections

7. Claim 28 is objected to as being dependent upon a withdrawn claim. Applicant is required to include the limitations of the method steps from claim 1 in the product claim to perfect the product by process claim.

Priority

8. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Shinkawa, et al. (Journal of Biological Chemistry, 2003. Vol. 278, pages 3466-3473, as cited on the IDS filed October 30, 2008) as evidenced by Cartron, et al. (Blood, 2002. Vol. 99, pages 754-758).

The claims recite therapeutic antibodies having high effector activity obtained from the method of claim 1, wherein said antibodies have on their glycosylation site of the Fc region, glycanic structures having a fucose content/galactose content ratio less

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than 0.6. The claims also recite pharmaceutical compositions comprising therapeutic antibodies having high effector activity obtained from the method of claim 1, wherein said antibodies have on their glycosylation site of the Fc region, glycanic structures having a fucose content/galactose content ratio less than 0.6 and at least one excipient and wherein the pharmaceutical composition comprises at least 50% of a monoclonal antibody for which the glycanic structures borne by the glycosylation site of the Fc region have a fucose content/galactose content ratio less than 0.6, and wherein the antibody is directed against a non-ubiquitous normal antigen, or an antigen of a pathological cell or on a pathogenic organism for humans, wherein said antibodies are IgGs.

Applicant is reminded that the intended use of a product claim carries no patentable weight. See MPEP 2111.02. Thus, the intended use of the claimed antibodies as a therapeutic is given no patentable weight.

Shinkawa, et al. teach KM3065 antibodies which have higher antibody dependent cellular cytotoxicity (ADCC) (e.g., “high effector activity”) than the parent Rituxan™ antibody (page 468 column 2 and figure 1b) and have a fucose content/galactose content ratio of 0.258 (see table 1; fuc 0.8/gal 0.31=0.258). Shinkawa, et al. also teach the KM3065 antibody is an IgG1 antibody that binds to CD20, a non-Hodgkin’s lymphoma antigen (page 3468, 2nd column) Shinkawa, et al. teach the purified antibodies were placed in a buffer composition the same as that for Rituxan™ (page 3467, 1st column). Cartron, et al. teach a humanized anti-CD20 monoclonal antibody (Rituxan™) administered in a pharmaceutical composition for the

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treatment of non-Hodgkin's lymphoma (page 755 1st column). Thus, buffer composition of Shinkawa, et al. is a pharmaceutical composition as evidenced by Cartron, et al.

Regarding the product by process, MPEP 2113 states "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, since the antibody of Shinkawa, et al. has a higher ADCC activity than the parent antibody and a fucose content/galactose content ratio less than 0.6, all the limitations of the claim have been met.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

December 3, 2008

/David J Blanchard/
Primary Examiner, Art Unit 1643